Page 3 Dkt: 44.P001

## IN THE CLAIMS

Please amend the claims as follows:

- 1. (Currently Amended) A patch device adapted for use in the transdermal administration to a patient of a composition including, or consisting of, dimethylformamide (DMF), the patch consisting of a layered construct adapted to be adhered to the skin of a patient and defining a depot cavity for the composition to be administered between a proximal layer and a distal layer thereof, which proximal layer is adapted in use to be located in intimate contact with the skin of the patient and which distal layer is in use disposed on the outer side thereof, the distal layer being characterized in that it is comprises a composite layer having a first layer which is flexible and is-made form of an and elastomeric silicone material bad which substantially is partially permeable to that the composition to be administered; and a second layer which is impervious to said composition, so that in use the composition may be disposed in the cavity and permeate from there through the proximal layer to be absorbed through the skin- into the body of the patient, the proximal and distal layers being bonded to portions of each other by means of silicone adhesive or by vulcanising, and the proximal layer being further characterised in that it is flexible and made of said elastomeric silicone material and is partially permeable to the composition, so that in use the composition may be disposed in the cavity and permeates from there through the proximal layer to be absorbed through the skin into the body of the patient, the proximal and distal layers being bonded to portions of each other by means of silicone adhesive or by vulcanizing, the proximal layer being further characterized in that its permeability to the irritating substance or component of the composition to be administered to the human or animal is less than the permeability of the human or animal skin, as the case may be, to such irritating substance or component; said layered construct further comprising an impervious membrane adhered to the distal layer, wherein the chemical composition of the proximal and distal layers are the same and the distal layer is modified by the application thereto of a thin impervious layer which is impervious to the components of the composition to be applied by means of a patch.
- 2. (Cancelled)
- 3. (Cancelled)

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Serial Number: 10581827

Title: PATCH

Filing Date: May 23, 2007

Dkt: 44.P001

Page 4

4. (Currently Amended) The A-patch-according to of claim 1 suitable for use in the

administration of DMF to a patient and characterized in that the proximal layer of the patch has a

permeability to DMF, such that DMF which is, in use, located in the cavity between the layers

will be released through the proximal layer at a rate below the rate which it is absorbed through

the skin of the patient to which the patient is in use applied, thereby substantially preventing

building up of DMF in direct contact with the skin of the patient.

5. (Previously Presented) The patch of claim 1 which is adapted to be adhered to the skin of

a patient by having a peripheral edge zone of the proximal layer which is provided with a

pharmaceutically acceptable adhesive layer, which adhesive layer is covered by means of a

conventional peel-off cover sheet during storage

6. (Previously Presented) The patch of claim 4 in which the layers of a patch intended to be

used for the administration of dimethylforamide as such, or of a pharmaceutical preparation

containing dimethylforamide as a penetration enhancing agent, are of the same chemical

composition and are made from vulcanizates of silicone.

7. (Previously Presented) The patch of claim 4 wherein the composition of the layer

intended for use as a proximal layer in a patch for use in the administration of DMF as such, or

of a pharmaceutical preparation containing DMF as a penetration enhancing agent, is produced

to have permeability to dimethylforamide of not more than 9 mg DMF/cm<sup>2</sup>/hour.

8. (Previously Presented) The patch of claim 1 in which the cavity defined between the

proximal and distal layers of the patch construct is preferably in use filled with a solid filler

material to serve as a carrier for the pharmaceutically active substance or composition received

therein.

9. (Previously Presented) The patch of claim 1 characterized in that it provides a passage

through the distal layer or layers, through which passage of the substance or composition to be

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Serial Number: 10581827 Filing Date: May 23, 2007

Title: PATCH

Page 5

Dkt: 44.P001

administered to the patient may in use be introduced into the cavity of the patch after the patch

has been placed on the patient.

10. (Currently Amended) The patch of claim 9 wherein the passage is in part constituted by a

self reclosing nipple or port formation integrally moulded with the distal layer of the patch

construct, or part thereof, to present an access opening on the outer surface of the patch into

which the sprout-like needle mounting of as a conventional syringe may in use be received to

introduce the substance or composition to be administered into the cavity via the passage.

11. (Currently Amended) The patch of claim 1 wherein the construct further includes a self

adhesive mounting layer having a surface presenting a skin adhesive, which adhesive layer is

typically during pre-use storage the product covered by a peelable cover layer also overlies, and

hence seals off, the proximal layer of the construct until it is exposed by peeling off the cover

layer.